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510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the BClear™, Targeted PhotoClearing™ System, is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) summary.

Applicant:	Lumenis Inc.
Address:	1249 Quarry Lane, Suite 100 Pleasanton, CA 94566
Contact Person:	C. Robert Payne, Jr., P.E.
Telephone: Fax:	(925) 249-8031 (925) 249-8010
Preparation Date:	May 24, 2002
Device Trade Name:	BClear™
Common Name:	Localized, narrow band ultraviolet phototherapy equipment
Classification Name:	Ultraviolet lamp for dermatologic/skin disorders (see 21 CFR 878.4630).
Legally Marketed Predicate Devices:	Lumenis Inc., BClear, Targeted PhotoClearing System (K011197, K020591); PhotoMedex, the parent of AccuLase, Inc., XTRAC™ Excimer Laser Phototherapy System, AL7000 (K011382, K992914, K003705).
System Description:	The BClear, Targeted PhotoClearing System, is an ultraviolet light source and energy delivery system that provides targeted energy to the treatment site while avoiding unnecessary exposure to non-affected tissue. The light source is contained within a protective console. The complete system also includes a handpiece connected to the console via an umbilical. Timing and dosing parameters and an interface to other system features are controlled from a display panel on the console. The delivery

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	system allows UV-B light to pass through the handpiece to selectively treat skin and nail lesions without exposure to the healthy skin.
Intended Use of the Device:	The BClear, Targeted PhotoClearing System, is a medical ultraviolet lamp and delivery device intended for the treatment of leukoderma. The BClear, Targeted PhotoClearing System, is also indicated for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. The BClear, Targeted PhotoClearing System, is intended for use on all skin types (I – VI).
Substantial Equivalence:	Currently published clinical data supports UVB treatment of hypopigmented or depigmented skin (leukoderma). The intended use of the BClear, Targeted PhotoClearing System, is within the scope of the predicate devices. The BClear and predicate devices use UV-B phototherapy for the treatment of dermatoses. The BClear, Targeted PhotoClearing System, is currently indicated for treatment of psoriasis, vitiligo, atopic dermatitis (eczema) and seborrheic dermatitis in 510(k)s K011197 and K020591.
Performance Data:	None. The technological specifications of the BClear, Targeted PhotoClearing System, are the same or very similar to those of the claimed predicate devices. The BClear, Targeted PhotoClearing System, has the same indications for use for which the claimed predicates have been cleared. Therefore, performance data is not required.
Conclusion:	Based on the foregoing, the BClear, Targeted PhotoClearing System, is substantially equivalent to the legally marketed, claimed predicate devices for the purposes of this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2002

Lumenis, Inc.
C. Robert Payne, Jr., P.E.
Director of Regulatory Affairs and Quality Assurance
1249 Quarry Lane, Suite 100
Pleasanton, California 94566

Re: K021762
Trade/Device Name: BClear™
Regulation Number: 878.4630
Regulation Name: Ultraviolet lamp for dermatologic/skin disorders
Regulatory Class: Class II
Product Code: FTC
Dated: May 24, 2002
Received: May 29, 2002

Dear Mr. Payne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as setforth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K021762

Device Name: BClear™

Indications for Use:

The BClear™, Targeted PhotoClearing™ System, is a medical ultraviolet lamp and delivery device intended for the treatment of leukoderma. The BClear, Targeted PhotoClearing System, is also indicated for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. The BClear, Targeted PhotoClearing System, is intended for use on all skin types (I – VI).

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR (per 21 CFR 801.109) Over-the-Counter Use ___

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021762